Rec'd 10/12/88 SB
Copies to Sandra, Dave. Doug R. has copy.

ASARCO

0161087

EAST HELENA PLANT
J. B. Davis
MANAGER

Nov 1 - Dave & I met & MSU. Doug's attempting to get a response. See Record of Nov 1.

Nov. 14 - Doug called me. No help from USDA yet. I will call Director there.

Nov. 16 - I called Jon N. We're still working on it... we'll keep in touch.

October 5, 1988

Dave: Please provide MSU's Recl. Res. Unit with a copy and request a written response to this letter and the attached memo from Weston (9/26).
SB

Mr. Scott Brown
Remedial Project Manager
U.S. Environmental Protection Agency
Federal Building - Drawer 10096
301 S. Park
Helena, MT 59626

Dear Scott:

The completed Step 1 Cattle Tissue Sampling Task has investigated lead, arsenic, and cadmium metal levels in two herds nearest the ASARCO East Helena Plant and one control herd near the Townsend area. The results from the EPA split samples seem to suggest that the 4.0 ppm trigger criteria for cadmium levels in the kidney tissue of all three herds has been exceeded. These preliminary results would appear to warrant initiation of the Step 2 Sampling Task for five additional test herds except for the fact that the control herd revealed similarly elevated cadmium levels in their kidney tissue. This unexpected situation has prompted the need to review the origin, rationale, and validity of the U.S. Department of Agriculture - Food Safety Inspection Service internal directives used as the trigger for the Step 2 Cattle Tissue Sampling Task.

WESTON has completed their assessment into the origin of the trigger levels for metals in beef. A copy of that report is enclosed for your review. The report concludes that there is no known documentation of the rationale for the USDA action levels or internal directives. Current FDA investigations have focused on daily intake per kg. of body weight as opposed to an absolute action level value in food products.

The critical question which must be addressed is whether the information prepared as part of the Step 1 Cattle Tissue Sampling Task will be adequate to prepare a Comprehensive Endangerment Assessment. I have discussed the contents of WESTON's enclosed assessment, as well as the sampling protocol of the Step 1 Cattle Tissue Sampling Task, with Mr. Charles Morgan of Environmental Sciences and Engineering, Inc. (ESE). ESE has been charged with the task of preparing the Comprehensive EA. Mr. Morgan has advised me that the information assembled as part of the Step 1 Cattle Tissue Sampling Task will be adequate to conduct the

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Fax No: (406) 227-7175

Comprehensive EA. Mr. Morgan suggested that market basket survey information, which may be available for Helena Valley beef from the Department of Agriculture, may be helpful in augmenting the Sampling Task results.

Once you have reviewed the enclosed report, feel free to contact me so that the project team can discuss these findings.

Sincerely,

Jon C. Nickel
Industrial Quality Manager

JCN:ps
Enclosure
cc: D. Rogness

We're not satisfied. Weston hasn't demonstrated. See Record of 11/1/88

Response required

WESTON
MANAGERS DESIGNERS/CONSULTANTS
215 UNION BOULEVARD
SUITE 600
LAKEWOOD, CO 80228
PHONE: (303) 980-6800

0161089

MEMORANDUM

TO: Jon Nickel, ASARCO
Scott Brown, EPA
Doug Rogness, MDHES
Dave Bunte, CH2M HILL

FROM: Kevin Harvey, WESTON

DATE: September 26, 1988

SUBJECT: Origin of "trigger" levels for metals in beef.

As a review, the Cattle Tissue Sampling Task, described in the ASARCO Smelter Phase II RI Work Plan, is divided into two sampling steps. Step 1 involved the sampling of two herds nearest the smelter as represetative of the potential worst case. Step 1 would also serve as a screening phase to determine if additional sampling would be necessary. Step 2 would involve sampling an additional five herds at varying distances away from the smelter throughout the Helena Valley. It was proposed that Step 2 cattle tissue sampling be triggered if at least one observation in either of the Step 1 test herds is in excess of the USDA arsenic, cadmium and/or lead criteria presented below.

Criteria used by the USDA Food Safety Inspection Service to evaluate trace metal levels in animal meat products for human consumption.

Established action levels for arsenic in cattle.

Kidney, Liver	2.7 ppm
Muscle	0.7 ppm

Written internal directives regarding suspect levels for cadmium and lead.

Kidney, Liver	4.0 ppm

These "trigger" criteria were derived from "internal written directives" which originated from the U.S. Department of Agriculture - Food Safety Inspection Service in Washington, D.C. Our original point of contact with the USDA - FSIS was Dr. Kirk Biddle. Dr. Biddle provided these internal directives to the EPA ASARCO/RI project team during the Phase I cattle work. EPA oversight suggested the use of these directives as trigger criteria during the development of the Phase II RI Work Plan.

The results from ASARCO's lab regarding the main body of samples have not been delivered at the time of this writing; however, results from EPA split samples suggest that the 4.0 ppm cadmium level in kidney tissue has been exceeded. This prompted an inquiry into the origin, rationale and validity of the USDA-FSIS internal directives used as the trigger for Step 2 cattle tissue sampling.

In response to these questions, this memo records information gathered via telephone calls to USDA and Food and Drug Administration (FDA) personnel. The main conclusions are that there is no known documentation of the rationale for the USDA action levels or internal directives, and that current FDA investigations focus on daily intake per Kg of body weight as opposed to absolute action level values in food. Some guidelines, albeit uncertain ones, are in use by the FDA.

Summaries of the phone conversations with FDA personnel are presented below.

1) Dr. Kirk Biddle, FDA (formerly USDA), 202/472-5701

Biddle worked with the USDA from April 1984 to October 1986. Doug Dollhopf contacted him there during ASARCO Phase I investigations, and recorded the USDA arsenic, cadmium and lead guidelines based on that contact.

We spoke with Biddle on June 13, 1988. He currently works in the FDA. He said that one of his major frustrations while working at USDA was in trying to locate documentation for various "internal directives" within the Residue Evaluation Branch. He found no information on the Pb and Cd guidelines.

Biddle suggested that we call Mr. Michael Bolger to get perspectives on the FDA's involvement with assessment of metals in beef.

2) Michael Bolger, FDA, 202/472-5705

Although the FDA has no explicit regulatory role regarding metal levels in beef, Bolger's office is involved with some total intake studies of Pb and Cd.

The guidelines that he uses are provided by the Joint Expert Committee on Food Additives (JECFA). This is part of the Food and Agriculture Committee of the World Health Organization. Last year JECFA submitted new maximum total Pb intake levels for children. The current guidelines are:

Children - 3.5 ug/kg of body weight/day
Adults - 7.0 ug/kg of body weight/day

When we spoke to Bolger on June 13, 1988, he agreed to send a copy of "Technical Report 751" which records these guidelines.

EPA did a study on air quality which examined all Pb intake pathways. That work referred to the FDA total diet studies which conclude that food/beverage/water make up about 50% of humans total Pb intake. That would be 1.75 ug for children and 3.5 ug for adults. Bolger also cited other work which attributes 83% of the food/beverage/water intake to food.

Bolger cautioned that his group uses that Pb intake figure as an upper end amount to back-extrapolate to blood levels. Such calculations yield blood levels of 28 ug/dl. However, there are new health data which suggest that toxicity problems can appear at Pb levels of 10 ug/dl. Thus, all the Pb guidelines are considered to be in somewhat of a state of flux.

The FDA also uses JECFA provisional values for investigations of Cd intake. For Cd, the guideline is based on work done at the Carolinska Institute in Sweden in the early seventies by Frieburg, and updated by Schellstrom of the same group. There is a critical Cd level which can accumulate in the human renal cortex before toxicity problems begin. That level is believed to be 200 ug/g. Back calculations to daily ingestion rates (assuming diet is the primary Cd intake route) could then yield guideline levels for foods. EPA has written this work up and Bolger agreed to send us the appropriate documents. There is dispute about the 200 ug/g kidney accumulation level, so Cd, like Pb, is subject to regulatory uncertainty.

We called Bolger's office again on September 14, 1988 to inquire again about the requested documents. He is on leave until September 19. Dr. Henry, who is acting in Bolger's place during his absence, was unable to locate the documents Bolger

promised to send. She did provide two text references which they use frequently in their work:

Carson, Alice and McCann. 1986. Toxicological and Biological Monitoring of Metals in Humans. Lewis Pub.

Frieburg, Nordberg and Vouk. Handbook on the Toxicology of Metals. Elsevier.

The Montana State University Library does not have these books.

We managed to finally get through to Bolger again and he has sent the documents he promised us back in June. Copies of these documents are attached.

In closing, we have done little to justify the use of the USDA internal directives for cadmium and lead in cattle tissues. This memo does not propose an alternative to the use of these guidelines. Perhaps a meeting to discuss the next phase of the cattle investigation task is in order just as soon as the main body of tissue data is received from the ASARCO Salt Lake Labs.

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Rec'd from
Michael Bolger
Sept. 1988
FDA

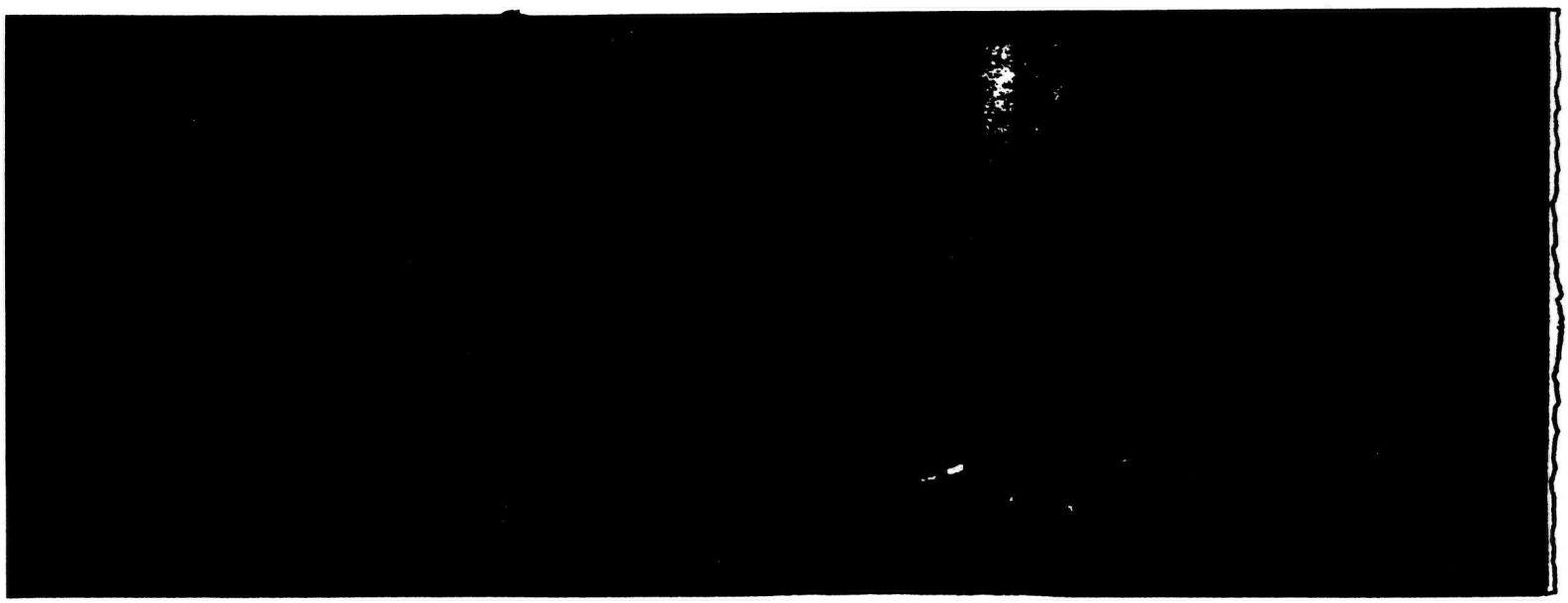
This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the World Health Organization or of the Food and Agriculture Organization of the United Nations

Evaluation of certain food additives and contaminants

Thirtieth Report of the
Joint FAO/WHO Expert Committee on
Food Additives

World Health Organization
Technical Report Series
751

World Health Organization, Geneva 1987



reported to be produced in dogs by magnesium trisilicate, (*b*) long-term studies on talc demonstrated to be free from asbestos-like particles; and (*c*) the development of a satisfactory method for estimating asbestos-like particles in talc and magnesium trisilicate.

In 1976, at the twentieth meeting, the Committee reiterated the need for a long-term study on talc of an acceptable specification before an ADI could be recommended (Annex 1, reference *41*). The Committee required short-term studies by 1980 to differentiate between the medicinal magnesium trisilicate and the insoluble magnesium silicate used in food processing, and allocated magnesium silicate a temporary ADI "not specified".

In 1980 (Annex 1, reference *53*), the Committee extended the previous temporary ADI "not specified" for talc (Annex 1, reference *32*) and requested a long-term study for 1983. Also in 1980, studies available to the Committee showed that talc was not mutagenic *in vitro* or *in vivo*. The temporary ADI "not specified" of magnesium silicate was extended to 1982 because certain short-term studies requested were not available. In 1982 (Annex 1, reference *59*), no additional information was made available on magnesium silicate. However, the existing tentative specifications were revised to exclude the presence of magnesium trisilicate. Thus, in 1982, the Committee reallocated the ADI "not specified" for magnesium silicate. This decision was confirmed in 1985 (Annex 1, reference *70*, section 2.2.2).

In 1983 (Annex 1, reference *62*), talc was removed from the agenda since no new data were available. Revised specifications on talc were available to the Committee at the present meeting, indicating a satisfactory method for estimating asbestos-like particles in the talc used in food processing by the use of transmission electron microscopy. The Committee was informed that food-grade talc has a solubility of less than 10 g/litre in water and does not contain magnesium trisilicate.

In view of these clarifications, the Committee decided to withdraw the previous request for a lifetime feeding study, provided that the talc used in food processing complied with the new specifications. The Committee allocated an ADI "not specified".

No toxicological monograph was prepared.

The Committee was aware that there is usually a requirement for asbestiform particles to be excluded from food-grade talc. However, the Committee received information suggesting that the light microscopy method previously specified for detecting asbestos in talc was incapable of achieving the degree of accuracy required by the limit specified. The Committee was not able to identify a reliable but simple alternative method, with the exception of transmission electron microscopy, as identified above. Therefore, the Committee stressed the need to develop a practical method that can be used to detect asbestos in talc on a routine basis at the levels required (see section 2.2.4).

The existing specifications were revised and designated as "tentative".

3.7 Contaminants

3.7.1 *Lead (evaluation of health risk to infants and children)*

Lead was previously evaluated by the Committee at the sixteenth meeting (Annex 1, reference *30*). A Provisional Tolerable Weekly Intake (PTWI) of 3 mg of lead per person, equivalent to 50 µg/kg of body weight, was established at that time. The Committee had indicated that this level did not apply to children. Because of the special concern for children and infants, the Committee at the present meeting evaluated the health risks of lead to this group. The Committee noted that valuable guidelines for evaluating these risks were provided by the previous principles governing the toxicological evaluation of metal contaminants (Annex 1, reference *30*, section 3.1), as well as by the principles contained in a recent report on the needs for a special approach to evaluating health risks during infancy and early childhood.[1]

The reason for special concern for children and infants relates to a number of factors, including: (*a*) higher metabolic rate than adults; (*b*) rapid rate of growth of the body; (*c*) individual differences in body composition; (*d*) immaturity of the kidneys, liver, nervous system, and immune systems; and (*e*) incomplete development of organs and tissues such as bones and brain. Since infants and children have higher energy requirements than adults, their intake of food, and hence of contaminants, per unit body weight is greater than that of adults. In addition, particular behavioural characteristics of children, such as heightened hand-to-mouth activity and the ingestion of non-food items (pica), may result in significant exposure to lead from non-food sources. Social and

[1] *Principles for evaluating health risks from chemicals during infancy and early childhood: the need for a special approach*. Geneva, World Health Organization, 1986 (WHO Environmental Health Criteria, No. 59).

cultural attitudes related to child rearing may influence exposure to non-food sources. Because the evaluation of the health effects of lead relates to exposure from all sources, any increase in the intake of lead from non-food sources (e.g., water and air) will reduce the amount that can be tolerated from food. It is important to identify the sources of exposure that may be of greater significance to infants and children than to adults, so that strategies for control may be developed.

Detailed information on sources of lead exposure is available.[1, 2] Sources include the general environment, the domestic environment, food, air, and drinking-water. The domestic environment is a particularly important source of lead exposure for children and infants, and includes indoor dust, top soil, and paint. The two publications below also provide detailed information on levels of lead in food and total intake for infants and children.[1, 2]

There is a large amount of information on the toxic effects of lead. The information used by the Committee for its evaluation has been largely derived from studies with infants and children. Adults normally absorb 5–10% of dietary lead, but children absorb lead from the diet with greater efficiency. **Children with lead intakes of 5 µg/kg of body weight per day are in positive balance and retain lead [redacted] lead at this level averages 40% of [redacted] has been estimated to be about 30% [redacted] However, metabolic studies indicate a negative balance when lead intake is less than 4 µg/kg per day.** The relationship between oral lead intake and blood lead levels is non-linear, with the greatest increases in blood lead levels occurring at the lower range of exposure.

The Committee considered the available information and, on the basis of evidence that a mean daily intake of 3–4 µg/kg of body weight of lead by infants and children is not associated with an increase in blood lead levels, established a PTWI of 25 µg/kg of body weight. This level refers to lead from all sources. A toxicological monograph was prepared.

The Committee recognizes that in some situations the PTWI may be exceeded and blood lead may reach a level of more than

[1] *Lead.* Geneva, World Health Organization, 1977 (WHO Environmental Health Criteria, No. 3).

[2] *Exposure of infants and children to lead.* Rome, Food and Agriculture Organization of the United Nations (Occasional Papers Series) (in preparation).

250 µg/litre. In such circumstances, the major source(s) of exposure should be determined and all possible steps taken to ensure that lead levels in food and contributions from other environmental sources are minimized. The following are possible strategies for achieving this.

The reduction or elimination of the use of lead solder and other lead-containing materials in equipment and containers coming into contact with food during its processing and handling can reduce lead contamination of foodstuffs.

Lead contamination of foods in tinplate cans with lead-soldered side-seams originates mainly from the solder. Such contamination can be reduced by operating the can-making equipment in such a way as to minimize the contamination of the inside of the can with the solder,[1] replacing high-lead solder by low-lead or lead-free solder, and lacquering the cans after soldering. Other ways of reducing lead contamination of canned foods include: (*a*) using electro-welding or other techniques instead of soldering to manufacture the can; (*b*) using two-piece cans instead of three-piece cans; (*c*) limiting the level of lead permitted in the tin used to manufacture tinplate for food cans; and (*d*) replacing tinplate cans by other types of container.

Certain glazes used on ceramic foodware contain appreciable levels of lead. If such foodware is not fired correctly, it may release large amounts of lead into foods that come into contact with it, especially if they are acidic. **The contamination of foods with lead from this source can be reduced by using lead-free glazes.** Foodware can be checked for levels of leachable lead using one of the standardized methods now available.

Contamination of drinking-water with lead from plumbing systems can be eliminated by replacing the lead in such systems with other materials. If this cannot be done, contamination of soft water (pH 4.5–5.5) with lead from plumbing systems can be reduced by increasing the pH of the water to about pH 8.5 by the addition of lime.

In some circumstances, tetra-alkyl lead used as a petrol additive is a major source of environmental lead pollution. Lead in motor vehicle exhausts increases lead exposure of infants and young

[1] See: *Guidelines for can manufacturers and food canners.* Rome, Food and Agriculture Organization of the United Nations, 1986 (FAO Food and Nutrition Paper No. 36).

children in several ways. Elevated lead levels in air directly increase lead exposure via inhalation. Atmospheric deposition of lead on growing crops or the use of sewage sludge contaminated with lead from highway runoff as fertilizer on agricultural land can result in increased lead levels in foodstuffs and animal fodder, and thus can indirectly increase dietary exposure. This type of lead pollution can be reduced by decreasing or eliminating the use of lead compounds as petrol additives.

House paints manufactured in the past sometimes contained high levels of lead, and therefore it is prudent to warn the parents of young children about the serious health hazards associated with the ingestion of flakes of such paint. Similar considerations apply to the use of lead in cosmetics and toys.

The discharge of lead into the environment by industry (e.g., lead ore mines and primary and secondary lead smelters) and from waste disposal may give rise to high levels of pollution locally. If such pollution cannot be reduced, careful attention should be given to the problems inherent in the consumption of heavily lead-contaminated food produced in areas affected by such pollution.

High lead levels from environmental sources in dust and soil can result in increased ingestion of lead by young children due to sucking of contaminated fingers and mouthing or swallowing of other non-food items contaminated with dust. Simple measures, such as teaching young children to wash their hands before eating, can help reduce lead exposure from contaminated dust.

4. ESTABLISHMENT AND REVISION OF CERTAIN SPECIFICATIONS AND GENERAL METHODS

4.1 Specifications

4.1.1 *Anthocyanins (other than grape-skin)*

Although detailed information had been received only for anthocyanins derived from blackcurrants, the Committee noted the existence of products extracted from a variety of other materials and recognized the need to develop specifications that would cover all of them. New, tentative specifications were prepared for the product derived from blackcurrants and a request was made for information on: (*a*) the use of antioxidants in this product; (*b*) the level and method of assay; (*c*) degradation products; and (*d*) a chromatographic identification test.

4.1.2 *Calcium disodium ethylenediaminetetraacetate*

The existing tentative specifications were revised and the "tentative" qualification was deleted.

4.1.3 *Carob bean gum*

The Committee was asked to consider the inclusion of limits on solvent residues in the specifications for carob bean gum. However, no information was provided on the use of solvents or their residues. The existing tentative specifications were revised and maintained as tentative, pending receipt of information on solvents.

4.1.4 *Citric and fatty acid esters of glycerol*

The Committee requested information on the assay procedure for determining the sum of citric acid, fatty acids, and total glycerol present. It also requested information on the method for measuring fatty acids. The existing tentative specifications for citric and fatty acid esters of glycerol were revised and the "tentative" qualification was maintained.

4.1.5 *Heptane*

The Committee noted that the product formerly referred to as heptane is in fact a mixture of hydrocarbons with the predominant general formula C_7H_{16}. The existing tentative specifications were revised and the name was changed to "heptanes". The "tentative" qualification was deleted.

4.1.6 *Lecithins*

The Committee received a request to make provision for hydrolysed lecithin within the specifications for lecithins. Insufficient information on the precise method of manufacture and identity of the hydrolysed product was provided to justify the request. The existing tentative specifications for lecithins were revised, the name was changed to "lecithin", which is the name in common use, and